

heterologous promoter not related to the retroviral vector, said promoter regulating, after infection of the target cell, expression of at least one of the coding sequences being inserted into the body of the vector; and

a packaging cell line harboring at least one retroviral or recombinant retroviral construct coding for proteins required for said retroviral vector to be packaged.

28. (Twice amended) A producer cell producing a retroviral particle, the producer cell comprising a retroviral vector and a DNA construct coding for proteins required for the retroviral vector to be packaged, said retroviral vector comprising in 5' to 3' order, a) a 5' long terminal repeat region of the structure U3-R-U5; b) one or more sequences selected from coding and non-coding sequences; and c) a 3' long terminal repeat region, wherein the U3 region comprises a heterologous promoter not related to the retroviral vector, said promoter regulating, after infection of the target cell, expression of at least one of the coding sequences being inserted into the body of the vector.

31. (Amended) The retroviral vector according to Claim 1, wherein said [regulatory elements and promoters are] promoter is target cell specific in [their] its expression.

#### REMARKS

##### Interview

Applicants' Attorney would like to thank Examiner Brusca for the helpful and courteous interview with Applicants' Attorney which was conducted at the Patent Office on June 8, 1999.

##### Claim amendments

As indicated in the Continued Prosecution Application (CPA) Request Transmittal being filed concurrently herewith, Applicants have requested entry of the unentered amendment under 37 C.F.R. § 1.116 mailed on May 6, 1999 to the Patent Office for filing in the nonprovisional prior application.

In addition, Claims 1, 17 and 28 have been amended to more clearly indicate the "5' to 3' order" of the elements of the claimed retroviral vector. Support for the amendment can be found, for example, in Figure 1 of the subject application. As discussed during the interview, such

amendment distinguishes over the prior art of record which discloses a gene linked to a promoter inserted into a partially deleted U3 region upstream of the 5' R region, or in the alternative, a gene linked to the promoter inserted into the body of the vector (Faustinella *et al.*); replacement of a wild type U3 region upstream of the 5' region with a corresponding region from a closely related retrovirus which drives expression of a gene inserted into the body of the vector (Couture *et al.*); and the absence of a U3 region upstream of the 5' R region (*i.e.*, the SIN vector) and insertion of a promoter and gene into the body of the SIN vector (Mee *et al.*).

In the Advisory Action mailed from the Patent Office on May 17, 1999 in the prior application (the Advisory Action), the Examiner states that Claim 7 has been amended to depend on canceled Claim 6, and a comma should be inserted in line 7 of Claim 7. Claim 7 has been amended to depend from Claim 31 and to include a comma in line 7 before the term "Mouse".

In the Advisory Action, the Examiner states that Claim 13 has been amended to result in a grammatically incorrect sentence. Claim 13 has been amended to be grammatically correct.

#### Substitute Declaration

In the Advisory Action, the Examiner states that the declaration is defective. Applicants are filing an executed Substitute Declaration concurrently herewith.

#### CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (781) 861-6240.

Respectfully submitted,

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